

## Targeted Site Reviews on Financial Conflict of Interest Observations

### Background:

The Targeted Site Review (TSR) program is an NIH initiative that focuses specifically on compliance with the Financial Conflict of Interest (FCOI) regulations (42 CFR Part 50 Subpart F) as they pertain to NIH grants. The TSRs are part of NIH's oversight responsibilities and were developed to determine if: (1) grantee institutions are fully and correctly implementing the FCOI regulation, and (2) reporting requirements are being met. The TSRs were conducted by the NIH Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, Office of Extramural Research. NIH conducted 18 TSRs in FY 2006 representing approximately \$4 Billion in FY2005 research grant awards, about 25 percent of the NIH budget allocated for research grants that year.

The purpose of this document is to provide the wider grantee community with observations made during the TSRs to serve as a resource in evaluating the implementation of the Federal FCOI regulation.

### Methodology:

The site review team prepares for the visits by reviewing FCOI policies and other pertinent documents provided by the participating grantee institutions prior to the site review. During the one-day site review institutional officials are engaged in discussions about the FCOI program (e.g., its organization, policies, and procedures). The team also meets with faculty and investigators who have had experience with the institution's FCOI program, preferably related to an NIH grant, to determine their understanding of their reporting responsibilities and institutional requirements. The institution is asked to select all individuals that meet with the site review team. At the end of the day, the site review team provides their observations, identifying areas of noncompliance and recommendations concerning implementation. If areas of noncompliance are noted, the institution will be expected to formally address and resolve the issues after the site review. We were pleased to receive feedback from participating institutions that the TSRs were helpful and constructive.

### Observations:

We found no instances of intentional noncompliance. The institutions that participated in the TSRs implemented the Federal regulation thoughtfully and with diligence. We found a solid awareness of the importance of compliance with the FCOI regulation and, perhaps as a result, mature, effective FCOI programs. We observed several institutions that have developed sophisticated electronic systems to manage FCOI; these systems provide a wide spectrum of management support from communicating with other institutional databases to tracking financial disclosures and providing training modules replete with case studies. It is important to note that neither the Federal regulation nor NIH require institutions to manage their programs in a particular manner, as long as the process used is effective for the institution.

We found that the most common compliance issues center around the appropriate definition of “investigator” and institutional reporting requirements. We generally characterize these two areas as implementation issues that result from the practicalities of establishing procedures to implement the FCOI regulation.

- Definition of Investigator

We observed that some institutions define “investigator” too narrowly and therefore inconsistently with the FCOI regulation. The FCOI regulation defines investigator as the principal investigator and any other person who is responsible for the design, conduct, or reporting of funded research, and it includes the investigator’s spouse and dependent children (42 CFR § 50.603). The regulation is very broad in its definition of investigator, and we therefore continue to encourage institutions to consider the roles, rather than the titles, of those involved in research and the degree of independence with which those individuals work. It is incumbent upon the institution to determine which individuals are subject to the requirements of the FCOI regulation. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk that an unidentified financial conflict of interest may compromise the research enterprise increases.

- Reporting

Institutions are required to report identified financial conflicts of interest (but not the nature of the interest or other details) prior to the expenditure of any funds under the grant award and assure that the interest has been managed, reduced or eliminated. Further, institutions must report any interest identified subsequently to the initial report under the award within 60 days of that identification (42 CFR § 50.604(g)(2)). We observed that institutions have the most difficulty with identifying and reporting newly identified financial conflicts and receiving disclosures from investigators who later join the project. However, the site reviews reaffirmed that education is key in ensuring that investigators comply with the FCOI requirements by understanding their responsibilities in the process.

Other compliance issues observed:

- No provision for subrecipient monitoring to ensure that identified conflicts are reported through the prime grantee to NIH
- No consistent reporting process in place
- Grant applications submitted prior to collecting significant financial interests from investigators
- Grant funds expended prior to reporting identified financial conflicts of interest to NIH

The site review team also made implementation suggestions. These are suggestions and should not be construed as requirements but may be considered effective practices:

- Develop clear financial conflict of interest policy and procedures that are accessible and include:
  - Definition of terms
  - Enforcement actions for noncompliance
  - Delineation of roles and responsibilities for:
    - Faculty and staff

- Compliance activities (e.g., reporting, collecting and reviewing financial disclosures, maintaining records, etc.)
  - Oversight (e.g., subrecipients)
- Records retention requirements
- A point of contact for questions
- Provide educational opportunities/materials for faculty and staff to ensure that all understand their roles and reporting responsibilities
- Ensure that financial disclosure forms are clear and easily understood
- Implement a follow-up process to ensure compliance with COI management plans, when appropriate